

### **REMARKS**

Claims 1-44 are pending. In accordance with the foregoing, independent claims 1, 16, 31 and 44 are amended as supported, for example, by paragraph 43 of the originally-filed specification. Claims 1-4, 9, 16-19, 24, 31, 34-35, and 40 are amended to correct a typographical error, namely to correctly replace the plural form "media" with the singular "medium". In the above referenced Office Action, claims 1-44 stand rejected.

Claims 1, 2, 5, 7-12, 16-17, 20, 22-28, 31, 36, and 38-41 stand rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman (U.S. 6,004,269). Claim 1 relates to a method of locating a target site for delivering a therapy to a patient, comprising "advancing the delivery device within the first site; delivering a contrast medium from a distal end of the delivery device within the first site to locate the target site by observing the direction of the flow of the delivered contrast medium in the first site away from the target site; and further advancing the delivery device from the first site upstream through the direction of the flow into the targeted site." Rosenman teaches that a radioopaque contrast medium may be delivered after anchoring a device in tissue to confirm location. As such, Rosenman clearly discloses delivering a device to a location without using a contrast agent, anchoring the device, then optionally delivering the contrast agent to confirm the location of the device. Thus Rosenman is not locating the locating using the contrast agent since the location must have already been located in order to have delivered the device to it. In contrast to Rosenman, the method of claim 1, as amended, involves locating the target site before the device is positioned in the target site, thus facilitating advancement of the device into the target site. While the use of a contrast agent to visualize anatomic structures in and of itself is not new, the injection of contrast agent in the prior art generally relies on the flow of contrast agent into a structure to identify the shape and location of the structure relative to other structures, e.g., the contrast agent flows with the direction of blood flow through a blood vessel allowing the path of the vessel to be identified. In contrast to prior art methods, the target site in the claimed methods is located by observing the direction of the flow of the delivered contrast medium away from the target site into the first site. Because of the directional

flow of the blood, the delivered contrast medium in the first site does not flow through the target site. However, the direction of flow of the contrast medium delivered within the first site allows the target site to be identified even though the contrast medium is not delivered into the target site itself. The device can then be advanced into the target site by advancing the device "upstream" through the direction of the flow of the contrast medium in the first site. Rosenman merely delivers a contrast agent after already locating and arriving at a target site. Rosenman is devoid of teaching delivering a contrast medium in a first site to identify a target site by observing the direction of flow of the contrast medium in the first site, then advancing the delivery device upstream through the direction of the flow of the contrast medium into the target site. For at least this reason, the Applicant submits that Rosenman fails to anticipate independent claims 1, 16, and 31. Applicant respectfully requests withdrawal of the rejection.

Claims 1-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman in view of Niazi (U.S. 6,638,268 B2). Niazi fails to remedy the deficiency of Rosenman relating to a method including locating a target site by observing the direction of the flow of the delivered contrast medium in the first site away from the target site and advancing a device into the target site by advancing the device upstream through the direction of the flow of the contrast medium. Accordingly, Applicant respectfully requests withdrawal of the rejection based on the combination of Rosenman and Niazi.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman in view of Leiden. The Examiner admits that Rosenman does not teach locating the coronary sinus ostium by the direction of flow of the delivered contrast medium within the heart. Applicant submits that Rosenman does not teach or suggest locating any target site based on the direction of flow of the delivered contrast medium in a first site as discussed above. The Examiner makes the conclusory statement that Rosenman teaches a contrast-injection navigation method. Applicant respectfully traverses in that Rosenman's optional contrast injections are performed after placement of the device at a location, not during navigation to the location. As discussed above,

Rosenman clearly teaches confirming a location, not navigating to or locating a location using contrast injection.

The Examiner relies on Leiden to disclose locating the coronary sinus ostium. While Leiden describes fluoroscopic guidance to advance a catheter to the coronary sinus ostium, Leiden fails to remedy the deficiency of Rosenman relating to delivering a contrast medium in an atrium and locating the coronary sinus ostium by observing the direction of flow of the contrast medium in the atrium away from the ostium. Leiden merely uses imaging, without the use of a contrast medium, to identify the catheter location relative to anatomical structures. Accordingly, neither Rosenman nor Leiden teach or suggest locating the coronary sinus ostium by the direction of flow of the delivered contrast medium within the heart. Applicant respectfully requests withdrawal of the rejection.

Applicant asserts that the remarks presented herein are fully responsive to the Office Action and are sufficient to overcome the rejections presented in the Office Action. However, there may be other arguments to be made as to why the pending claims are patentable. Applicant does not concede any such arguments by having not presented them herein. Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

June 18, 2008  
Date

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